(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 453 234 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
30.09.1998 Bulletin 1998/40

(51) Int. Cl.[6]: **A61M 25/00**

(21) Application number: **91303368.4**

(22) Date of filing: **16.04.1991**

(54) Hemodialysis Catheter

Hämodialysekatheter

Cathéter d'hémodialyse

(84) Designated Contracting States:
DE ES FR GB IT

(30) Priority: **20.04.1990 US 513491**

(43) Date of publication of application:
23.10.1991 Bulletin 1991/43

(73) Proprietor: **Cook Incorporated**
Bloomington IN 47402-0489 (US)

(72) Inventors:
- **Uldall, Peter Robert**
  Willowdale, Ontario, M2L 1M2 (CA)
- **DeBruyne, Michael Paul**
  Bloomington, Indiana 47408 (US)

(74) Representative:
Johnston, Kenneth Graham
5 Mornington Road
Woodford Green Essex, IG8 OTU (GB)

(56) References cited:
EP-A- 0 093 887
WO-A-86/07267
DE-A- 2 912 852
US-A- 4 643 711

EP 0 453 234 B1

Printed by Xerox (UK) Business Services
2.16.3/3.4

Description

This invention relates to hemodialysis catheters.

One prior art hemodialysis plain tube catheter has provided good blood flow and can be left in place in the external or internal jugular vein for months or years. The flow characteristics are not ideal, but the catheter appears to maintain patency better than tapered tube catheters with side ports. The main problem with a plain tube catheter is its cross-sectional shape, which is similar to a double-barrelled shotgun with squared off ends, making it unsuitable for percutaneous insertion over a wire guide, or reinsertion into the same site. Peel-away sheath can be used for percutaneous insertion of catheters, but an 18 French sheath, required to accommodate large catheters, is judged to be undesirable.

Heretofore, it has always been considered necessary for positive pressure return lumens to extend beyond and thus downstream of the negative pressure intake lumens of a hemodialysis catheter. However, clots tend to adhere to the outside wall of the shorter intake lumen.

High efficiency dialysis requires the use of two large diameter lumens with an external cross-sectional dimension which is not too large for vascular access. One short-term catheter includes a simple double-D lumen configuration. The walls are thin, and the equal area lumens make full use of the available space, but in order to keep its shape during high flow rate dialysis, the catheter is made of relatively stiff material which is unsuitable for long-term placement. If silastic material is used for the intake lumen it would collapse under the influence of the strong negative intake pressure. Furthermore, the septum between the two lumens is pulled into the negative pressure lumen, thereby adversely changing the cross-sectional area in the two lumens as well as the blood flow rates therethrough.

Temporary or short-term catheters of the double-D configuration are universally used in large numbers but tend to get blocked. The use of stiff material causes the catheter to kink or buckle when bent more than 180°, resulting in obstruction, and cracking or splitting, and may be responsible for vein penetration injuries.

Silastic® catheters with the double-barrelled shotgun configuration (two cylindrical lumens side by side) are remarkably resistant to kinking even when bent sharply through 180°. Cylindrical lumen achieve maximum flow for the smallest wall surface area and minimum clotting. They avoid the sharp corners in the wall of the double-D configuration.

The side-by-side open-ended design of the long-term catheter has much less tendency to block, but has not been used as a temporary catheter since it cannot easily be introduced percutaneously. The circular intake lumen of the long-term catheter is similarly recessed back from the distal end of the return lumen to minimize blood recirculation. A problem with this is that the wall of the extended positive pressure return lumen provides a surface for clots to adhere. In an attempt to solve this blockage problem, the walls of the negative pressure intake lumen are provided with side ports. However, these side ports may actually encourage clotting.

The long term catheter typically employs a fixed-position dacron cuff which may not be conveniently positioned to stabilize the catheter. Removal of the catheter and release of the dacron cuff requires a new incision and dissection of the cuff by a surgeon. Dissecting the cuff from ingrown tissue invariably leads to bleeding, which may be hard to control.

U.S.A-4643711 discloses a hemodialysis catheter as defined in the preamble of claim 1,

WO-A-8607267 discloses a collapsible catheter for insertion into a patient.

According to the present invention there is provided a catheter as defined in claim 1.

When inserted in a vein, the collapsed lumen returns to its original shape.

The return lumen is thick enough to withstand the positive pressure of the returning blood without stretching.

The negative pressure intake lumen preferably is longer than the positive pressure return lumen at the distal ends, and thus reduces the accumulation of blood clots and resulting blockage with only a minimal increase in blood recirculation between the two lumens.

To eliminate the seepage of blood between the tubular members where they penetrate the vein wall, the catheter can be segregated into distal and proximal segments. For percutaneous insertion, the distal segment advantageously includes the different thickness walls for collapsing the thin-walled positive pressure return lumen about the negative pressure intake lumen and inserting the collapsed distal segment through a smaller diameter introducer sheath. Extending proximally from the distal segment, the proximal segment advantageously has a cross-sectional shape of a generally elliptical character to form a leak proof fit when inserted into the vein wall. Furthermore, both of the segments are formed from a biocompatible material, such as silastic®, for long-term use and have a predetermined durometer for pushing the catheter through the introducer sheath and blood vessel.

Brief description of the drawings

FIG.1 depicts a catheter;

FIG.2 depicts a cross-sectional view of the distal segment of the catheter of FIG.1 along the line 2-2;

FIG.3 depicts a cross-sectional view of the distal segment of the catheter of FIG.1 in a collapsed state and positioned in an introducer sheath; and

FIG.4 depicts a cross-sectional view of the proximal segment of the catheter of FIG.1 along the line 4-4.

Depicted in FIG.1 is a dual lumen hemodialysis catheter 100 for use in an extracorporeal treatment.

This vascular access catheter is percutaneously inserted in a blood vessel, such as preferably the jugular or femoral vein, for either short-term or long-term hemodialysis treatment of the patient. The jugular access site is preferable to the subclavian vein because it is much less likely to cause subclavian vein thrombosis. Subclavian vein thrombosis is a serious long-term disability for a patient on dialysis if it is not diagnosed and successfully treated at an early stage, because it interferes with A-V fistula construction in the ipsilateral arm, leading to a permanently swollen congested arm as long as the fistula is functioning. Internal jugular vein thrombosis is probably not common after internal jugular cannulation, but it causes no disability even if it occurs and is not treated, except that the patient loses a potential access site.

The catheter basically comprises a dual lumen main body 101 attached to a single lumen, arterial clamping limb 104 and a single lumen, venous clamping limb 105 via interconnecting manifold 106. For connection to extracorporeal treatment equipment, two female Luer lock connectors 107 and 108 are connected in a well-known manner to arterial and venous clamping limbs 104 and 105, respectively. The main body of the catheter includes a distal segment 102 and a proximal segment 103 extending proximally therefrom and is comprised of a flexible biocompatible material such as 70 durometer silicon or silastic®. Distal segment 102 includes a thick-walled, negative pressure, first elongated tubular member 201 and a shorter, thin-walled, collapsible, positive pressure, second elongated tubular member 202 attached laterally thereto. The catheter further includes lockable clamps 117 and 118 for clamping arterial and venous clamping limbs 104 and 105, respectively. One such clamp is the BETA-CAP clamp. Qosina slide clamps are also acceptable.

Catheter 100 also includes an anchoring grommet 116 having a ring-like collar 111 positioned around and slideably moveable along proximal segment 103. Flange 112 and 113 extend laterally from the collar and have respective apertures 114 and 115 formed therein to insert sutures therethrough. The grommet is positioned on the proximal segment where it crosses the supraclavicular fossa. Sutures placed through the apertures secure the catheter to the surrounding tissue. The shape of the grommet permits capture of the catheter without compressing it. The smooth rounded flanges allow the grommet to be pulled out with the catheter when it is removed. The anchoring sutures will tear out of the flanges and the only thing left inside the patient will be the sutures themselves.

The overall length of the main body of the catheter from the manifold to the distal tip thereof depends on the insertion site selected by the physician. When inserted in the right jugular vein, the main body of the catheter from manifold to tip is preferably 26cms in length with an 11cms distal segment. For the left jugular site, the main body of the catheter is approximately 30cm in length with the distal segment being 15cm. As suggested, the distal segment 102 includes a collapsible second tubular member 202 for inserting the distal segment with stiffening cannula 109 inserted in first tubular member 201 over wire guide 110 through a well-known smaller diameter peel-away introducer sheath (not shown). The introducer sheath should be no more than 10cm in length. This will allow the distal segment to be inserted into the sheath with the distal tip protruding slightly beyond the distal end of the sheath before it is peeled away.

Second tubular member 202 is attached laterally to first tubular member 201 and collapsible thereon. First tubular member 201 (FIG.2) includes a first wall 203 surrounding first longitudinal passageway 204 included therein. This first longitudinal passageway 204 is designated as a negative pressure intake lumen for receiving blood from the vessel of a patient for hemodialysis treatment. By way of example, the thickness of first wall 203 is approximately 0.05 cm (0.020") with the cross-sectional diameter of passageway 204 being approximately 0.2 cm (0.080"). The distal end of lumen 204 may be outwardly tapered to prevent clotting and the collection of blood clots thereon. The dimensions of first tubular member 201 and lumen 204 allow for blood flow rates of 350-400ml per minute without collapsing.

Second tubular member 202 includes a second longitudinal passageway 205 with a second wall 206 positioned thereabout. The thickness of second wall 206 is approximately 0.0254 cm (0.010") with the second longitudinal passageway having a cross-sectional diameter of approximately 0.2 cm (0.080"), being approximately equal to that of the first passageway 204. In an uncollapsed state, the maximum cross-sectional dimension of distal segment is approximately 0.53 cm (0.210") plus allowances for fabrication and slip coating 207, which will pass through an 18 French 0.599 cm (0.236") aperture. Second passageway 205 is designated as the positive pressure return lumen for returning blood to the vessel of the patient. The cross-sectional areas of first and second passageways 204 and 205 are substantially equal to provide approximately equal flow rates to and from the patient. The distal segment 102 also includes slip coating 207 which acts as a lubricant to insert the distal segment 102 through the introducer sheath. One such slip coating is a slippery-when-wet hydrophilic coating that is commercially available from Hydromer Inco., Whitehouse, New Jersey. The slip coating is applied to the outside surface of distal segment 102. This hydrophilic slip coating is wetted during the insertion procedure to provide a slippery surface for easier insertion through the peel-away introducer sheath. Furthermore, the presence of blood or other fluids in the introducer sheath further lubricates the collapsed distal segment as it is being inserted therethrough. This further eases the percutaneous insertion of the catheter when inserting a collapsed catheter having an 18 French uncollapsed cross-sectional dimension through

a 12 French introducer sheath. Another lubricious slip coating is Dow Corning medical-grade silicone fluid spray, applied by the physician just prior to percutaneous insertion of the catheter.

Experimentally, a 30cm thin-walled, positive pressure member of a 70 durometer silicon material catheter was able to tolerate a blood flow of 500ml per minute and a negative pressure of 300mm/Hg without collapsing when flows were reversed, and it was used as a negative pressure lumen. In clinical practice, the ability to reverse the flows is important if on occasion the thick-walled lumen fails to provide adequate out flow. The dialysis treatment community has been demanding these flow rates, but until now has not been provided with catheters to provide these flow rates. Experiments indicate that blood flow rates of 400ml per minute are attainable with arterial and venous pressure barely exceeding 200mm of mercury.

The cross-sectional shape of the passageways are circular to maintain maximum laminar fluid flow for a given wall surface area. The introduction of a smaller radius into the cross-sectional shape of the passageway typically provides opportunities for the blood flow to become turbulent and increases the risk of clotting.

A number of competing factors are involved with the dimensions associated with the wall thicknesses and lumen diameters. The tubular members must be thin and flexible enough for insertion into the vascular system without kinking or collapsing in operation. First wall 203 of first tubular member 201 must be thick enough to withstand the negative pressures inwardly exerted thereon by modern hemodialysis machines without collapsing during intake of blood from the patient. Thinner, positive pressure lumen wall 206 must be thick enough to withstand the positive pressures outwardly exerted thereon without stretching. The diameter of the passageways should be as large as possible to provide adequate flow rates as demanded by hemodialysis. Lastly, the maximum cross-sectional dimension of the catheter must be minimal for percutaneous insertion into the blood vessel such as through a 12 French 0.4 cm (0.158") peel-away introducer sheath. As a result, the thickness of the first wall 203 is preferably twice as thick as that of the second wall 206. Furthermore, the thickness of the first wall 203 may range from one and a half to three times as thick as that of the second wall 206 of positive pressure lumen 205.

This thin wall construction permits the collapse of the second tubular member 202 about the first tubular member 201 as depicted in FIG. 3. In the collapsed state, the catheter typically having a maximum cross-sectional dimension of 18 French can be percutaneously inserted with stiffening cannula 109 over wire guide 110 into a blood vessel through a much smaller 12 French diameter peel-away introducer sheath 301.

The cross-sectional shape 401 (FIG.4) of the proximal segment 103 is formed to provide a tight fit between the main catheter body and the vascular access insertion site. Preferably, the cross-sectional shape is elliptical to prevent the seepage of blood from the vascular access site along the outside surface of the proximal segment of the main catheter body. Respective negative and positive pressure lumens 204 and 205 extend entirely through proximal segment 103.

To insert the dual lumen catheter using the well-known Seldinger technique, a wire guide 110 is inserted through an introducer needle into the accessed vein. The introducer needle is removed, and a 12 French sheath mounted on a dilator is directly inserted over the guidewire into the vein. Stiffening cannula 109 is inserted through the negative pressure lumen of the arterial clamping limb 104, proximal segment 103, and out the distal tip end of distal segment 102. The catheter and stiffening cannula are inserted over wire guide 110 and through the peel-away sheath with the thin-walled second tubular member 202 collapsed. The peel-away sheath is removed after the distal segment is inserted through the sheath into the vein. A short distal portion of the elliptically shaped proximal segment 103 is then inserted through the venous access site into the vein, thereby establishing a relatively tight and leak-proof seal.

Grommet 116 is mounted onto the catheter by passing it over the distal tip, after the catheter has been pulled up through the subcutaneous tunnel and before the catheter is inserted through the sheath into the vein. Grommet 116 slides the distal segment and a length of proximal segment 103 and is placed strategically in the supraclavicular fossa and anchored to the subcutaneous tissue before the supraclavicular wound is closed. Final position of the grommet will vary in each patient according to how much length of the catheter is desired in the blood vessel.

To change the catheter, it will only be necessary to re-open the supraclavicular incision and remove the subcutaneous silk sutures which are anchoring the grommet in place. To remove the catheter without intending to replace it with another one in that same track, the catheter is subjected to a steady pull. This will tear the sutures out of the flanges of the grommet.

A number of alternative grommets may be slid over or attached to the proximal segment of the catheter for anchoring the catheter to surrounding tissue. The catheter may also include any number of other connectors or clamping devices for use with the arterial and venous clamping limbs.

Claims

1. A hemodialysis catheter comprising an elongated distal segment (102) comprising a first (201) and a second (202) elongated tubular member forming first and second passageway (204,205) of approximately equal cross-sectional areas, the first tubular member (201) having a first predetermined wall thickness, and the second tubular member (202)

having a second predetermined wall thickness, characterised in that said second tubular member (202) is laterally attached to said first tubular member (201); the first and second passageways (204,205) are of generally circular cross-section; the first and second wall thicknesses are each constant over their non-attached area; and the first wall thickness is sufficiently greater than the second wall thickness so that the second tubular (202) member is collapsible on the first tubular member (201) during insertion of the catheter into a patient.

2. The catheter of claim 1, wherein the first wall thickness is at least one and a half times as thick as the second wall thickness.

3. The catheter of claim 1 or 2, wherein the first wall thickness is up to three times as thick as the second wall thickness.

4. The catheter of claim 1,2 or 3, wherein the first passageway (204) comprises a negative pressure intake lumen and the second passageway (205) comprises a positive pressure return lumen, and wherein the first and second tubular members (201,202) are of respective first and second lengths, the first tubular member (201) being longer than said second tubular member (202) at the distal ends thereof.

5. The catheter of any one preceding claim, further characterised by a slip coating (207) about the distal end of the first and second tubular members (201,202).

6. The catheter of any one preceding claim, wherein another segment (103) of the catheter extends from the proximal end of the said distal segment (102) to the proximal end of the catheter and is generally elliptical.

7. The catheter of claim 4, wherein the distal end of the first passageway (204) is tapered.

Patentansprüche

1. Hämodialysekatheter, bestehend aus einem länglichen distalen Segment (102) mit einem ersten (201) und einem zweiten (202), einen ersten bzw. zweiten Durchgang (204, 205) mit ungefähr gleicher Querschnittsfläche bildenden, länglichen röhrenförmigen Glied, wobei dar erste röhrenförmige Glied (201) eine erste bestimmte Wandstärke und das zweite röhrenförmige Glied (202) eine zweite bestimmte Wandstärke aufweisen, dadurch gekennzeichnet, daß das besagte zweite röhrenförmige Glied (202) seitlich am besagten ersten röhrenförmigen Glied (201) befestigt ist, der erste bzw. zweite Durchgang (204, 205) jeweils einen im allgemeinen kreisförmigen Querschnitt aufweist, die erste bzw. zweite Wandstärke über den unbefestigten Bereich jeweils konstant ist, und die erste Wandstärke so viel größer als die zweite Wandstärke ist, daß das zweite röhrenförmige Glied (202) bei der Binführung des Katheters in den Patienten auf dem ersten röhrenförmigen Glied (201) kollabiert werden kann.

2. Katheter gemäß Anspruch 1, worin die erste Wandstärke mindestens 1 ½ Mal so dick ist wie die zweite Wandstärke.

3. Katheter gemäß Anspruch 1 oder 2, worin die erste Wandstärke bis zu drei Mal so dick ist wie zweite Wandstärke.

4. Katheter gemäß Anspruch 1, 2 oder 3, worin der erste Durchgang (204) ein Vakuumaufnahmelumen und der zweite Durchgang (205) ein Vakuumrückgabelumen aufweisen, und worin das erste bzw. zweite röhrenförmige Glied (201, 202) jeweils eine erste bzw. zweite Länge aufweisen, wobei das erste röhrenförmige Glied (201) an seinen distalen Enden länger als das besagte zweite röhrenförmige Glied (202) ist.

5. Katheter gemäß einem der vorhergehenden Ansprüche, weiterhin gekennzeichnet durch eine Gleitbeschichtung (207) um das distale Ende des ersten bzw. zweiten röhrenförmigen Gliedes (201, 202).

6. Katheter gemäß einem der vorhergehenden Ansprüche, worin sich ein anderes Segment (103) des Katheters vom proximalen Ende jenes distalen Segments (102) bis zum proximalen Ende des Katheters erstreckt und eine allgemein elliptische Form aufweist.

7. Katheter nach Anspruch 4, worin das distale Ende des ersten Durchgangs (204) verjüngt ist.

Revendications

1. Cathéter d'hémodialyse comprenant un segment distal allongé (102) comprenant un premier (201) et un deuxième (202) organes tubulaires allongés formant des premier et deuxième passages (204, 205) de sections transversales approximativement égales, le premier organe tubulaire (201) ayant une première épaisseur de paroi prédéterminée, et le deuxième organe tubulaire (202) ayant une deuxième épaisseur de paroi prédéterminée, caractérisé en ce que ledit deuxième organe tubulaire (202) est attaché latéralement audit premier organe tubulaire (201); les premier et deuxième

passages (204, 205) ont généralement une section transversale circulaire; les première et deuxième épaisseurs de paroi étant chacune constante sur leur superficie non attachée; et la première épaisseur de paroi est plus grande, dans une mesure suffisante, que la deuxième épaisseur de paroi, de sorte que le deuxième organe tubulaire (202) puisse s'affaisser sur le premier organe tubulaire (201) au cours de l'insertion du cathéter dans un patient.

2. Cathéter selon la revendication 1, dans lequel la première épaisseur de paroi est au moins une fois et demie plus épaisse que la deuxième épaisseur de paroi.

3. Cathéter selon la revendication 1 ou 2, dans lequel la première épaisseur de paroi est jusqu'à trois fois plus épaisse que la deuxième épaisseur de paroi.

4. Cathéter selon la revendication 1, 2 ou 3, dans lequel le premier passage (204) comprend une lumière d'admission de pression négative et le deuxième passage (205) comprend une lumière de retour de pression positive, et dans lequel les premier et deuxième organes tubulaires (201, 202) ont des première et deuxième longueurs respectives, le premier organe tubulaire (201) étant plus long que ledit deuxième organe tubulaire (202) au niveau de ses extrémités distales.

5. Cathéter selon l'une quelconque des revendications précédentes, caractérisé en outre par un revêtement de glissement (207) autour de l'extrémité distale des premier et deuxième organes tubulaires (201, 202).

6. Cathéter selon l'une quelconque des revendications précédentes, dans lequel un autre segment (103) du cathéter s'étend depuis l'extrémité proximale dudit segment distal (102) jusqu'à l'extrémité proximale du cathéter et est généralement elliptique.

7. Cathéter selon la revendication 4, dans lequel l'extrémité distale du premier passage (204) est conique.

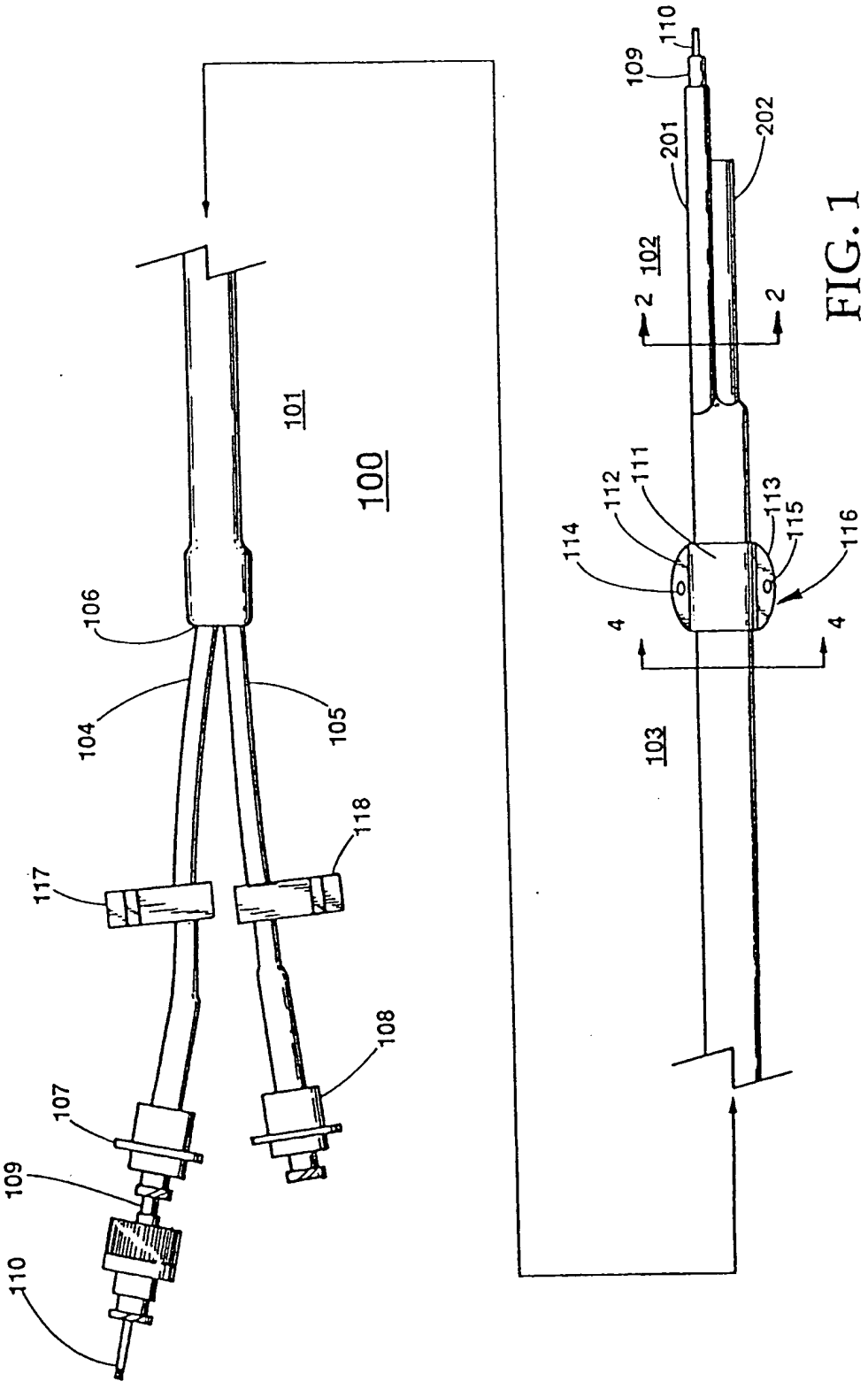
100
101
102
103
104
105
106
107
108
109
110
111
112
113
114
115
116
117
118
201
202
2
2
4
4

FIG. 1

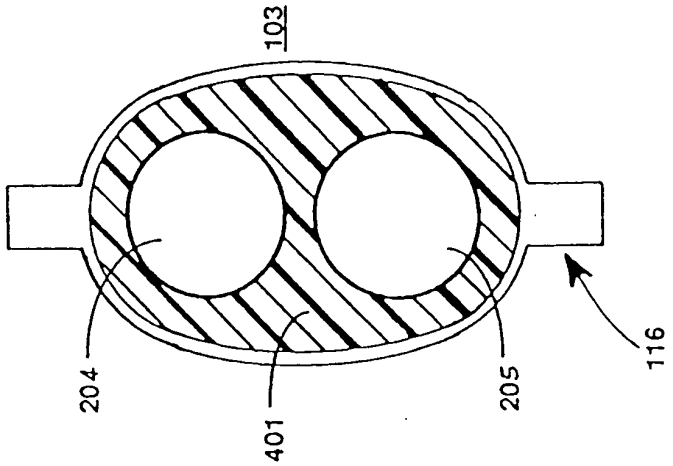

Fig. 4

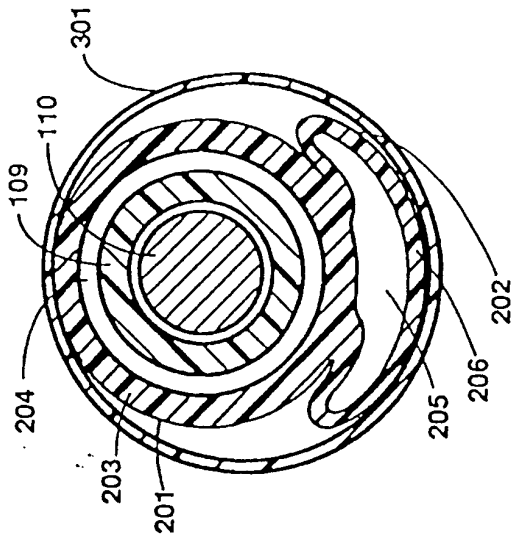

Fig. 3

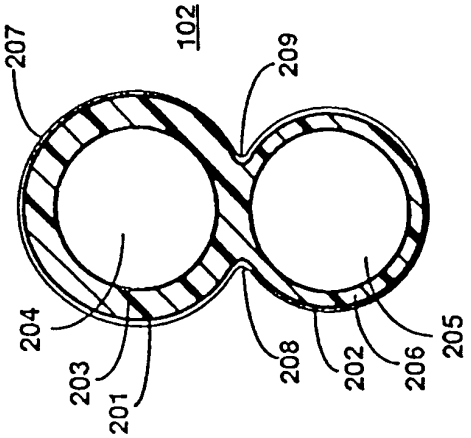

Fig. 2